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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/355,214	07/23/99	CHAN A	A-64383-2

NM12/0329

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EXAMINER	
ZITOMER,S	
ART UNIT	**PAPER NUMBER**
1655	4

DATE MAILED: 03/29/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev. 2/95)

1- File Copy

Office Action Summary

Application No.	Applicant(s)
09/355,214	CHAN et al.
Examiner	**Group Art Unit**
Stephanie Zitomer	1655

☒ Responsive to communication(s) filed on *Nov 22, 1999* .

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-22* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-22* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____ .

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____ .

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *3*

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Defective oath

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CAR 1.67(a) identifying this application by application number and filing date is required. See M.P.E.P. §§ 602.01 and 602.02. The oath or declaration is defective because the parent application, 08/819,013, and the grandparent application, 08/788,322 are incorrectly listed as abandoned and pending, respectively. The former has been patented and the latter has been abandoned.

Informalities

2. The disclosure is objected to because of the following informalities: In claims citing specific nucleotide or amino acid sequences in figures, the SEQ ID NO: should be included for clarity and specificity according to 37 CAR 1.821.

Appropriate correction is required.

Rejections under 35 U.S.C. 101 and 112, first paragraph: Lack of utility

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claim 16 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility. The BLNK protein, *per se*, and the nucleic acids encoding it have specific, substantial and credible utility as B cell-specific markers (page 19, lines 21-23). However, no use for the claimed "pharmaceutical composition comprising a BLNK protein" is stated in the specification. A "pharmaceutical composition" is intended for pharmaceutical use, i.e., as a drug or medication for treating a specific disease or condition. Yet the specification fails to identify any disease or condition treatable with a BLNK protein in a pharmaceutical composition.

Note that because the claimed invention is not supported by a specific asserted utility credibility cannot be assessed.

4. Claim 16 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, i.e., the claim is not enabled. The specification teaches that the claimed BLNK protein interacts with various B cell proteins including Grb2, PLCγ, nck, Vav and phospholipase C following BCR activation (page 19). It is stated further that a function of BLNK "is to modulate the ability of the B cell receptor to regulate calcium levels in the cell" (page 19, lines 7-9). However, modulation of BCR regulation of calcium levels is not shown to be a factor in any disease or condition treatable with a pharmaceutical composition comprising a BLNK protein nor has any other disease or condition been shown to be associated with the activity of a BLNK protein. Accordingly, undue experimentation would have required to enable the skilled artisan to practice the claimed invention. In *In re Wands*, 858 F.2d 731 at 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988) the Court identified factors to be considered in determining "undue experimentation". These factors include: (a) the nature of the invention; (b) the breadth of the claims; (c) the amount of direction or guidance presented; (d) the presence or absence of working examples; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the quantity of experimentation necessary. In the present case, the nature of the invention is such that the activity of the BLNK protein is not precisely stated in the specification or in the prior art and is largely speculative based on the ability to bind other B cell proteins. Claim 16 is exceedingly broad encompassing drugs or medications for treating an unidentified disease or condition associated with BLNK protein. No teaching or guidance or working examples of therapeutic use of BLNK protein are presented in the specification. While the level of skill in the molecular biology art at the time the application was filed was high, the level of unpredictability in the field was also high. Therefore, the quantity of experimentation that would have been required to enable the claimed pharmaceutical composition would have been undue beginning with identification of the specific activity of

BLNK protein in the B cells and of diseases or conditions which ensued from some aberration in the BLNK protein activity.

5. Claims 21 and 22 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility. The BLNK protein, *per se*, and the nucleic acids encoding it have specific, substantial and credible utility as B cell-specific markers as previously stated. However, the claimed "method for screening for a bioactive agent capable of binding to a BLNK protein" and "method for screening for a bioactive agent capable of modulating the bioactivity of a BLNK protein" do not comply with the 101 section of statute 35 because the asserted potential treatment utility for B-cell lymphomas and autoimmune diseases which have hyperactivated B cells (pages 19-20) is not supported by the disclosure.

6. Claims 21 and 22 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention methods are not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, i.e., the claims are not enabled. The specification teaches that the claimed BLNK protein interacts with various B cell proteins including Grb2, PLCγ, nck, Vav and phospholipase C following BCR activation (page 19). It is stated further that a function of BLNK "is to modulate the ability of the B cell receptor to regulate calcium levels in the cell" (page 19, lines 7-9). However, BCR bioactivity has not been precisely identified and is not shown to be a factor in any disease or condition. Therefore, the claimed methods for screening for bioactive agents that affect the activity of BLNK protein do not have a specific utility. Furthermore, the specification states that the basis for using BLNK protein as a target to screen for inhibitors is its <u>putative</u> critical role in BCR response (page 19, lines 28-29). Accordingly, undue experimentation would have required to enable the skilled artisan to practice the claimed invention methods. In *In re Wands*, 858 F.2d 731 at 737, 8 USPQ2d 1400, 1404 (Fed Cir. 1988) the Court identified factors to be considered in determining undue experimentation as stated above. In the present case, the nature of the invention is such that the activity of the BLNK protein is not precisely stated in the specification or in the prior art and is largely speculative based on the ability to bind other B cell proteins. So, too, is the association of BLNK protein with a

disease or condition. Claims 21 and 22 are very broad encompassing methods for screening for any agent that affects the binding or "bioactivity" of a BLNK protein in any way. The agents thereby identified are stated to have potential therapeutic use. While a general teaching of how to practice the claimed invention screening methods is presented in the specification no teaching or guidance or working examples of therapeutic use of "bioactive agents" derived therefrom is disclosed. While the level of skill in the molecular biology art at the time the application was filed was high, the level of unpredictability in the field was also high. Therefore, the quantity of experimentation that would have been required to enable the claimed screening assays would have been undue beginning with identification of the specific activity of BLNK protein in the B cells and of diseases or conditions which ensued from some aberration in the BLNK protein activity.

Rejection under 35 U.S.C. 112, first paragraph: Nonenablement

7. Claims 1-3, 7-14 and 16-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the recombinant BLNK protein having the amino acid sequence, SEQ ID NO:1 and its coding nucleotide sequence, SEQ ID NO:2, does not reasonably provide enablement for the large number of nucleic acids and proteins and nucleotide sequences which encode a BLNK protein, hybridize to the Figure 2 nucleotide sequence or which have a given percent homology to the disclosed nucleotide or amino acid sequences and methods, compositions and binding molecules involving BLNK nucleic acids or proteins or coding or amino acid sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims are drawn to any recombinant nucleic acid encoding any BLNK protein and to any BLNK protein, i.e., any "molecules which interact with either (*sic*) Grb2, PLC-γ or SYK" as stated in the last four lines at page 2 of the specification. The claims are further drawn to nucleic acids hybridizing to the nucleotide sequence of Figure 2, having at least 60% identity to the nucleotide sequence of Figure 2, the proteins encoded thereby and proteins having at least 50% homology to the amino acid sequence of Figure 1. Thus the claims encompass a very large number of nucleic acids and proteins only one of which in each category is disclosed. The specification states at page 5 that nucleic acids and proteins having a given percent

homology may be "determined using standard techniques known in the art, such as the Best Fit program... or the BLASTX program" and that "alignment may include the introduction of gaps in the sequences to be aligned". This loose description of how the claimed sequences may be found does not provide sufficient teaching or guidance to enable one skilled in the art to determine the specific sequences that are within the scope of the claims. No specific algorithm used for alignment nor the Gap or Gap Extension Penalties is disclosed. The court stated in *Amgen, Inc.* v. *Chugai Pharmaceutical Co. Ltd*, 18 USPQ2d, 1016,

> Conception of chemical compound requires that inventor be able to define compound so as to distinguish it from other materials, and to describe how to obtain it, rather than simply defining it solely by its principal biological property; thus, when inventor of gene, which is a chemical compound albeit a complex one, is unable to envision detailed constitution of gene so as to distinguish it from other materials, as well as method for obtaining it, conception is not achieved until reduction to practice has occurred, and until after gene has been isolated.

Additionally, in *Fiers v. Sugano*, 25 USPQ2d 1601 (CAFC 1993), the court stated

> specification containing statements that claimed DNA sequence is part of the invention and reference to a potential method for isolating the sequence does not describe the DNA itself, nor even demonstrate that the disclosed method would actually produce the DNA in question.

Therefore, it has been clearly established that a nucleotide or amino acid sequence which cannot be described by the applicant and the method of making the sequences is outside the scope of the enablement set forth in the specification. One of skill in the art cannot look to the prior art for guidance in making the claimed "homologous" sequences because the sequences of SEQ ID NOS: 1 and 2 are not found in the prior art nor are any sequences having the claimed homology to be found there. Although the level of skill in the art is high, PhD. or above, the level of unpredictability in the molecular biology art is also high. Absent specific teaching, the broadly claimed "homologous" sequences cannot be determined or even predicted, without undue experimentation, based on the examples in the specification

which enable only the sequences of SEQ ID NOS: 1 and 2. The Courts have established that

> A specification must be more than an invitation to experiment, i.e., applicant may not require persons skilled in the art to perform undue experimentation to achieve a successful result. See *In re Wright*, 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1933); *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970).

Further in *Wright*, *id.* at 1513:

> Although not explicitly stated in section 112, to be enabling the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without "undue experimentation". *In re Vaeck*, 947 F,2d 488 at 495, 20 USPQ2d 1438 at 1444; *In re Wands*, 858 F.2d 731 at 736-37, 8 USPQ2d 1400 at 1404; *In re Fisher*, 427 F. 2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (the first paragraph of section 112 requires that the scope of protection sought in a claim bear a reasonable correlation to the scope of enablement provided by the specification). Nothing more than objective enablement is required, and therefore it is irrelevant whether this teaching is provided through broad terminology or illustrative examples. *In re Marzocchi*, 439 F.2d 220, 223, 169 USPQ 367, 369 (CCPA 1971).

For all of foregoing reasons, therefore, the scope of the claimed invention is nonenabled.

Rejection under 35 U.S.C. 112, first paragraph: Lack of written description

8. Claims 1-3, 7-14 and 16-22 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims are drawn to a very large genus of recombinant BLNK protein species, species of nucleic acids encoding the protein and species of antibodies to the protein. In addition to enablement the first

paragraph of 112 requires a "written description". As set forth by the Court in *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, the written description must convey to one of skill in the art "with reasonable clarity" that as of the filing date applicant was in possession of the claimed invention. The specification describes the protein, BLNK1, and its splice variant, BLNK2, and discloses the amino acid sequence of BLNK1 as well as the nucleotide sequence encoding it. However, the specification is silent regarding the sequences of other BLNK protein and nucleic acid species to which the claims are drawn. Although degeneracy in the genetic code is understood in the art and codon usage for particular classes of organisms is known this is an inadequate basis for predicting the specific sequences claimed by applicant. The specification states at page 15 that "rabbit polyclonal" and "mouse monoclonal" antibodies to BLNK fusion proteins were made. However, these antibodies are not described: not as to their type nor the epitopes to which they bind nor the procedures by which they were made. Absent description of a reasonable number of sequence and antibody species the specification cannot convey to one of skill in the art that applicant possessed the large genus of claimed nucleotide and amino acid sequences and antibodies as of the date the application was filed.

Rejection under 35 U.S.C. 112, second paragraph: Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) The claims are indefinite in reciting the abbreviation "BLNK protein". To be definitive, the protein should be identified by its full name. If desired, the abbreviation may be recited in parentheses after the full name in claim 1 and used in subsequent claims.

(b) The claims are further indefinite in the name of the protein (anticipating its full recitation), "B-cell Linker Protein" (page 27), which is non-defining with regard to its structure, properties and function and because these limitations cannot be read into the claims from the specification. *In re Prater*, 162 USPQ 541, 550-551 (CCPA 1969).

(c) The claims are indefinite in failing to define the metes and bounds of the claimed invention. The skilled practitioner in the art would be unable to determine the scope of the claimed invention recombinant nucleic acid due to the nebulous name, "B-cell linker protein" and the lack of definition of the protein which it encodes.

Interpretation of claims

10. In the following rejections over the prior art the claimed "BLNK protein" is interpreted as "molecules which interact with either (*sic*) Grb2, PLC-γ or SYK" as stated in the last four lines at page 2 of the specification.

Rejections under 35 U.S.C. 102(b): Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1, 8, 11 and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagai et al. (J. Biol. Chem. (March 21, 1995) 270(12):6824-6829). The claimed recombinant nucleic acid encoding the BLNK protein (claim 1), Shc, and host cell transformed therewith (claim 8) are disclosed at page 6825, first paragraph, lines 17-20. The reference discloses that Shc interacts with Grb2 (abstract; see also page 6825, Results, second paragraph). The claimed recombinant BLNK protein (claim 11) is disclosed as Shc (page 6826, third full paragraph). The claimed polypeptide capable of specifically binding to a BLNK protein (claim 17) is disclosed as Grb2 (abstract). The claimed antibody that binds a BLNK protein (claims 18-19) is disclosed as an anti-Shc antibody (page 6825, second paragraph, line 13 and Figure 1 legend).

12. Claims 1, 2, 8, 10, 11 and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Jackman et al. (J. Biol. Chem. (March 13, 1995) 270(13):7029-7032). The claimed recombinant nucleic acid encoding a BLNK protein (claim 1) wherein the protein is a human BLNK protein (claim 2) and the host cell transformed therewith (claim 8) are disclosed at page 7030 at "Cloning..." in which the human BLNK protein is SLP-76 and the cell is a human Jurkat cell. The claimed method of producing a BLNK protein (claim 10) is

disclosed at page 7029, Materials and Methods, first paragraph. The claimed recombinant BLNK protein (claim 11) is disclosed as SLP-76 (abstract). The polypeptide capable of specifically binding to a BLNK protein (claim 17) is disclosed as pp76 and others which coprecipitated with Grb2 (page 7030, Figure 1). The claimed antibody that binds a BLNK protein (claim 19) is disclosed as antibody to human PLC-γ1 (page 7029, penultimate paragraph).

13. Claims 1, 8, 10, 11 and 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Richard et al. (Mol. Cell Biol. (Jan. 1995) 15(1):186-197). The claimed recombinant nucleic acid encoding a BLNK protein (claim 1) is disclosed as a cDNA encoding p62 and the host cell transformed therewith (claim 8) is a HeLa cell (page 187, paragraphs 3-6 of Materials and Methods). The claimed method of producing a BLNK protein (claim 10) and the recombinant BLNK protein (claim 11) are disclosed at page 187, paragraph bridging columns 1 and 2). The claimed polypeptide that binds a BLNK protein (claim 17) is disclosed as fyn in the method of using the polypeptide to detect the BLNK protein (claim 20) and the antibody (claims 18-19) as antibody that binds the p62 BLNK protein (page 189, Figure 2).

Rejection under 35 U.S.C. 102(e): Anticipation

> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

14. Claim 21 is rejected under 35 U.S.C. 102(e) as being anticipated by Morris et al. (5,770,421). Morris et al. disclose a method for screening for a bioactive agent capable of binding to the ALK protein. The ALK protein binds to PLCγ (column 37, lines 35-59) and therefore is a BLNK protein according to the definition at page 2 of the present specification (cited above at paragraph 10). The Morris et al. screening method comprises combining a BLNK protein and a candidate bioactive agent and determining the binding of the candidate agent to BLNK protein (column 15, lines 63-67).

Rejections under 35 U.S.C. 103(a): Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 1, 2 and 6-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagai et al., Jackman et al. or Richard et al. as applied to claims 1, 2 and 8 above, and further in view of Kaufman (4,740,461). The first three references collectively meet the limitations of claims 1, 2 and 8 as stated above. The claimed invention differs from Nagai et al., Jackman et al. and Richard et al. wherein the recombinant nucleic acid encoding a BLNK protein is in an expression vector comprising "transcriptional and translational regulatory DNA operably linked to DNA encoding a BLNK protein" and a host cell is transformed therewith. However, it was routinely practiced in the art to operably link transcriptional and translational regulatory sequences to the DNA encoding a protein to be produced by an expression vector in a host cell as taught, for example, by Kaufman (4,740,461) at columns 4-8 for promoters, enhancers, polyadenylation signal sequences, introns and translational activators. Applicant has admitted that mammalian and bacterial expression systems and methods for introducing exogenous nucleic acid into hosts was well known in the art (specification, page 13, line 14; page 14, lines 9-11, 16; page 16, lines 4-6). Accordingly, it would have been **prima facie** obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the recombinant nucleic acid of Nagai et al. with the teachings of Kaufman to obtain the claimed invention because the skilled practitioner in the art would have been motivated by the benefits taught by Kaufman of such regulatory sequences. For example, enhancers work in conjunction with promoters and activate transcription while being insensitive to position and orientation (column 6, lines

24-30). Translational activator products increase the rate or efficiency of translation (column 8, lines 55-59).

16. Claim 22 is rejected under 35 U.S.C. 103(a) as being unpatentable over Morris et al. (5,770,421) as applied to claim 21 above in view of the further teachings of Morris et al.. The claimed invention method differs from that of Morris et al. wherein the BLNK protein and candidate bioactive agent are combined with a protein selected from Grb2 and PLCγ and determining protein-protein binding wherein the absence of binding indicates that the agent is capable of modulating the bioactivity of the BLNK protein. However, Morris et al. teach that the ALK protein binds to PLCγ (column 37, lines 35-59). It would have been **prima facie** obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the screening method of Morris et al. with the further teachings of Morris et al. to obtain the claimed invention because the skilled practitioner in the art would have been motivated to assess the ability of the candidate bioactive agent to bind to ALK in the presence of its normal cognate protein, PLCγ, for the expected benefit of determining interference with normal binding which would have been only putatively determined by binding of the agent to the BLNK protein alone.

Statutory double patenting rejection

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

17. Claims 4-6 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3 of prior U.S. Patent No. 5,994,522. This is a double patenting rejection.

Double patenting obviousness-type rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent

possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 7-9 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-7 of U.S. Patent No. 5,994,522. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims are generic to the patent claims and it would have been obvious to the skilled artisan to provide nucleic acids encoding other BLNK proteins in an expression and host cell for the expected benefit of producing BLNK proteins in addition to those of the patent claims.

Prior art of interest

19. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The patent to Shin et al. (5,962,224) is cited for disclosure of the BLNK protein, p62.

Conclusion

20. No claim is allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephanie Zitomer whose telephone number is (703) 308-3985. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152. The official fax phone number for this Group is (703) 308-4242. The unofficial fax number is (703) 308-8724.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Stephanie W. Zitomer, Ph.D.
March 24, 2000

PRIMARY EXAMINER